in the labeling, is not less than 5.0 and not more than 7.5. It passes the identity test. The amoxicillin trihydrate used conforms to the standards prescribed by §440.3(a)(1).

(2) *Labeling.* In addition to the labeling requirements prescribed by §432.5 of this chapter, this drug shall be labeled ''amoxicillin for oral suspension''.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The amoxicillin trihydrate used in making the batch for potency, moisture, pH, amoxicillin content, concordance, crystallinity, and identity.

(*b*) The batch for potency, moisture, pH, and identity.

(ii) Samples required:

(*a*) The amoxicillin trihydrate used in making the batch: 12 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of six immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Assay for potency by either of the following methods; however, the results obtained from the iodometric assay shall be conclusive:

(i) *Microbiological agar diffusion assay.* Proceed as directed in §436.105 of this chapter, preparing the sample for assay as follows: Reconstitute the drug as directed in the labeling. Place an accurately measured representative portion of the sample into a suitable volumetric flask and dilute to volume with 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to give a stock solution of convenient concentration. Mix well. Further dilute an aliquot with solution 3 to the reference concentration of 0.1 microgram of amoxicillin per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in §436.204 of this chapter, except in paragraph (d) of that section, add 3 drops of 1.2*N* hydrochloric acid to both the sample and working standard solutions after the addition of 0.01*N* iodine solution. Prepare the sample as follows: Reconstitute the drug as directed in the labeling. Place an accurately measured aliquot (usually a single dose) into an appropriately sized volumetric flask and dilute to volume with distilled water. Mix well. Further dilute with distilled water to the prescribed concentration.

(2) *Moisture.* Proceed as directed in §436.201 of this chapter.

(3) *pH.* Proceed as directed in §436.202 of this chapter, using the suspension reconstituted as directed in the labeling.

(4) *Identity.* Proceed as directed in §436.311 of this chapter, preparing the sample solution as follows: From an aliquot of suspension prepared in accordance with the label, make either a 6.25:1 dilution for the 25-milligrams-per-milliliter dosage; or a 12.5:1 dilution for the 50-milligrams-per-milliliter dosage, with 0.1*N* hydrochloric acid. The slight dilution of the acid does not have a significant effect on the test.

[39 FR 34033, Sept. 23, 1974, as amended at 49 FR 3458, Jan. 27, 1984; 50 FR 19919, May 13, 1985; 54 FR 47351, Nov. 14, 1989]

§440.103c Amoxicillin trihydrate chewable tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Amoxicillin trihydrate chewable tablets are composed of amoxicillin trihydrate with or without one or more suitable lubricants, diluents, preservatives, drying agents, flavorings, and colorings. Each tablet contains amoxicillin trihydrate equivalent to either 125 or 250 milligrams of amoxicillin. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of amoxicillin that it is represented to contain. Its moisture content is not more than 6.0 percent. It passes the identity test. The amoxicillin trihydrate used conforms to the standards prescribed by §440.3(a)(1).

(2) *Labeling.* In addition to the labeling requirements prescribed by

§432.5 of this chapter, this drug shall be labeled ''amoxicillin tablets.''

(3) *Requests for certification; samples.* In addition to the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assay on:

(*a*) The amoxicillin trihydrate used in making the batch for potency, moisture, pH, amoxicillin content, concordance, crystallinity, and identity.

(*b*) The batch for potency, moisture, and identity.

(ii) Samples required:

(*a*) The amoxicillin trihydrate used in making the batch: 12 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 30 tablets.

(b) *Tests and methods of assay*—(1) *Potency*. Assay for potency by either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(i) *Microbiological agar diffusion assay*. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of tablets into a high-speed glass blender jar with sufficient 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to obtain a stock solution of convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot and dilute with solution 3 to the reference concentration of 0.1 microgram of amoxicillin per milliliter (estimated).

(ii) *Iodometric assay*. Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: Place a representative number of tablets into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 5 minutes. Further dilute with solution 1 to the prescribed concentration.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *Identity*. Proceed as directed in § 436.311 of this chapter, preparing the sample as follows: Using a mortar and pestle, grind a representative number of tablets into a fine powder. Dissolve an accurately weighed amount of this powder in 0.1*N* hydrochloric acid to give a solution containing 4 milligrams of amoxicillin per milliliter.

[45 FR 64569, Sept. 30, 1980, as amended at 50 FR 19919, May 13, 1985]

§ 440.103d Amoxicillin trihydrate and clavulanate potassium tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Amoxicillin trihydrate and clavulanate potassium tablets are composed of amoxicillin trihydrate and clavulanate potassium with or without one or more suitable lubricants, diluents, and binders. Each tablet contains amoxicillin trihydrate equivalent to either 250 or 500 milligrams of amoxicillin and clavulanate potassium equivalent to 125 milligrams of clavulanic acid. Its amoxicillin trihydrate content is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of amoxicillin that it is represented to contain. Its clavulanate potassium content is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of clavulanic acid that it is represented to contain. Its moisture content is not more than 7 percent if it contains 250 milligrams of amoxicillin and not more than 10 percent if it contains 500 milligrams of amoxicillin. It passes the dissolution test if the quantity *Q*, at 30 minutes, is 85 percent or greater if it contains 250 milligrams of amoxicillin and 75 percent or greater if it contains 500 milligrams of amoxicillin. The amoxicillin trihydrate conforms to the standards prescribed by § 440.3(a)(1). The clavulanate potassium conforms to the standards prescribed by § 455.15(a)(1) of this chapter.

(2) *Labeling.* In addition to the labeling requirements prescribed by § 432.5 of this chapter, this drug shall be labeled ''*amoxicillin and clavulanate potassium tablets*''.

(3) *Requests for certification; samples.* In addition to the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The amoxicillin trihydrate used in making the batch for potency, moisture, pH, amoxicillin content, concordance, crystallinity, and identity.

(*b*) The clavulanate potassium used in making the batch for clavulanic acid content, moisture, pH, identity, and clavam-2-carboxylate content.